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09/986,426	11/08/2001	Randal J. Kirk	54719.000011	5236

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Hunton & Williams
Suite 1200
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Washington, DC 20006

EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/986,426

Applicant(s)

KIRK ET AL.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-94 is/are pending in the application.
4a) Of the above claim(s) 76-94 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 54-75 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 54-75 are pending.

Papers

The amendments filed July 23, 2002 and November 19, 2002 have been received and entered. The change in power of attorney filed July 23, 2002, is noted.

Priority

Priority benefit to back to date of March 5, 1999, is noted.

Election/Restrictions

Applicant's election with traverse of Group I (claims 54-75) in Paper No. 12-03-03 is acknowledged. The traversal is on the ground(s) that each of the Groups are related and both Group I and Group II relate generally to the use of internalized domains or pockets of amino acids and manipulation of tertiary structure of an amino acid polymer and that art designations may or not be relevant to the examination process, as well as advantages to Applicant for pursuing only one application. This is not found persuasive because each Group is classified differently and because each polymer may possess or exhibit its own distinct and different intrinsic properties of conformational structure such as leading to different and distinct inventions as well as independent and distinct classification.

The requirement is still deemed proper and is therefore made FINAL.

Claims 76-94 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable

generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. noted above.

Information Disclosure Statement

The references submitted on the IDS filed July 23, 2002 have been considered.

Claim Objections

Claim 65 is objected to for not setting forth —of claim—before “64” at line 1. Further, claim 59 is objected to because of a grammatical error, therefore, —of—should be placed before “polypeptides” at line 2.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 recites the limitation "the formation of said interanlized domans or pockets" in lines 4-5, however, at line 2 only one domain or pocket is supported. There is insufficient antecedent basis for this limitation in the claims. Claims 55-75 are rejected for these reasons as well.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54-56, 59-60, 62, 66 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al.

Claims are drawn to a pharmaceutical composition comprising (i) an active agent and (ii) an amino acid polymer.

Peterson et al (also referred to as Peterson) teach a pharmaceutical composition comprising (i) an active agent and (ii) an amino acid polymer. Note the abstract. The polymer is disclosed to be a homopolymer contain glutamic amino acid or can be heteropolymeric and may comprise valine, alanine, leucine, etc.. Also note col. 4, lines 15-25 and 59. The polymer can be a mixture and of varied length. Also the active agent can be a hormone, note column 7, lines 65-68. Copolymers are disclosed at column 4, line 59 and gln (glutamine) and glu (glutamic acid) are disclosed at col. 3, and col. 4, all lines as well as col. 7, lines 10-25.

The claims appear to be identical to the cited disclosure and are therefore, considered to be anticipated by the teachings of the reference.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 57-58, 61, 63-65, 67-70 and 72-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. ('166), cited above, in view of Latham et al. ('227) and Kramer et al. (P3); all cited on enclosed PTO-1449 Forms.

Claims are further drawn to use of D-amino acids of 5-400 amino acid residues. The active agent can be iodothyronine. A copolymer can have a ratio between 3 and 4 and the composition further comprising an excipient which can be a filler, a lubricant, etc. The polymer can be a co-polymer of lysine and phenylalanine and agent can be hydrocortisone. The polymer has a free energy of folding between 3 kcal/mol and 50 kcal/mol. The release of the agent is in the small intestine or in the stomach. The polymer consists essentially of Cys, Pro, Glu and Tyr residues. Further the polymer can be a copolymer of glu and phe (phenylalanine) or lysine and phe ; and agent can be L-DOPA or aspirin. Also the polymer can be lysine.

Peterson et al are discussed above.

Latham et al iodothyronine polymers, note the abstract and col. 3, lines 10-55. Further, Latham et al teach 5-400 amino acid residues and an excipient. A copolymer can have a ratio between 3 and 4 is suggested by the teachings of Latham at col. 16, lines 15-20. Further, polymers and/or copolymers are suggested, if not taught, at col. 3, lines 15-30, wherein phe and glu are specifically disclosed at lines 27 and 25. The release of the agent can be in the stomach which may include the small intestine. Note col. 4, lines 9-36. Note oil is a lubricant. Further, Cys, Pro, Glu and Tyr are disclosed at col. 3, lines 10-28 as well. Lysine polymer is further disclosed, note col. 3, line 25.

Kramer et al teaches use of D-amino acids, note page 10623, all lines for purposes of intestinal absorption via use of polymer carriers of D-amino acids and an bioactive agent.

Claims differ from Peterson et al in that specific limitations of molar ratios of 5 to 400 amino acid residues and D-amino acid residues polymers as well as delivery of the same to stomach and small intestine, etc. are not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of Peterson et al, and Latham et al, Kramer et al in order to provide for the combinations and molar ratios of 5 to 400 amino acid residues and D-amino acid residues polymers as well as delivery of the same to stomach and small intestine since each of the prior art references teach or at least suggest individually and when combined together teach or suggest the claimed subject matter. Each of the ingredients required by the claimed composition are clearly disclosed by the cited prior art combination. Molar ratio between 3 and 5 are at least

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suggested and well within the skill of an ordinary artisan to determine for purposes of optimization of the composition. The determination of the energy of folding is also routine in the art and one of skill would have been motivated to determine such folding since the proteins are being used as a delivery mechanism or carrier and such folding properties would have been desirable to obtain by an ordinary artisan. The claims are prima facie obvious over the cited prior art.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware
February 21, 2004